UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

DEFENDANTS' MOTION IN LIMINE TO PRECLUDE
ARGUMENTS FROM PLAINTIFFS' CLOSINGS

Defendants move to exclude certain arguments from Plaintiffs' closing arguments. As explained more fully below, Plaintiffs should not be permitted to make arguments to the jury that do not have any support in the trial record or that are unfairly prejudicial.

1. "At-Risk" Launch

Plaintiffs may argue that Teva (or another generic manufacturer) would have launched a generic version of Nexium "at risk." *See, e.g.*, 11/18/14 Tr. at 89–90 (Plaintiffs eliciting testimony about Teva's alleged proclivity for at-risk launches); 11/21/14 Tr. at 147–48 (same); ECF No. 1306 at 17 ("[T]he jury could conclude from the evidence adduced at trial and reasonable inferences therefrom that Teva would have launched generic Nexium at risk"). Any such argument should be excluded.

First, there is no evidence that Teva (or another generic manufacturer) had plans to launch a generic version of Nexium at risk. The trial record has no evidence that Teva (or any generic company) planned to launch generic Nexium at risk. This alone precludes Plaintiffs from raising this argument in closings.

Second, such argument would be contrary to the Court's ruling on directed verdict that "there is no adequate evidence that any of [the Nexium] patents would be adjudicated invalid. There is no such evidence," 11/21/14 Tr. at 4, and contrary to Plaintiffs' own concession that

they "haven't offered competent proof that the patents as [a] matter of fact are invalid," 11/20/14 Tr. at 38. Under these facts, an at-risk launch would be wrongful; Plaintiffs have no right to lower Nexium prices brought about by the market entry of infringing generic Nexium. Under the Court's ruling on patent validity, and Plaintiffs' concession about the lack of evidence, any early entry Plaintiffs posit must be pursuant to a license from AstraZeneca.

2. Value of Exclusive License Granted to Ranbaxy

The Court should preclude Plaintiffs from arguing that the exclusive license to Ranbaxy had certain value. Plaintiffs have failed to account (including through expert testimony) for the fact that Ranbaxy's exclusive license has not yet and *may never be* triggered because Ranbaxy must *first* obtain final FDA approval and did not do so before May 27, 2014 —in which event the no-AG agreement would be worth *nothing*—or discounted for that possibility. Plaintiffs introduced documents estimating (based on various assumptions) the value to AstraZeneca of launching an authorized generic and documents from Ranbaxy estimating the value of Ranbaxy's launch of generic Nexium, but Plaintiffs made no effort to discount these figures by the probability that the alleged "payment" would materialize.

By contrast, the undisputed evidence is that this alleged "payment" would not materialize. In fact, subsequent events have shown that it would not realize the value of the exclusive license, because, as the Court ruled, Ranbaxy "in fact never had the capacity to bring its generic to market." 10/21/14 Tr. at 42; *see also* 11/19/14 Tr. at 26 (testimony of J. Deshmukh that Ranbaxy never made any profit from the settlement agreement). Plaintiffs offered no evidence to account for these conditions on the value of the exclusive license and offered no evidence quantifying the likelihood that Ranbaxy would ever realize any value from the exclusive license. Without that, Plaintiffs have no evidence of the expected value of the exclusive license and cannot argue that the exclusive license has any value.

3. API Supply and Tolling Agreements with Ranbaxy

Under *Actavis*, payments for "fair value" may not give rise to antitrust liability. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013). Plaintiffs have not presented any evidence that AstraZeneca's agreements with Ranbaxy for supply of esomeprazole API and capsules (tolling) were anything other than for "fair value."

Plaintiffs have introduced no evidence that the value of the API supply and tolling agreements to Ranbaxy exceeded fair value for the goods and services Ranbaxy provided. The undisputed evidence in the trial record is that the API and capsules supply agreements were negotiated at arms' length and provided a low-cost alternative to AstraZeneca's sources at the time. *See* 10/29/14 Tr. at 25 (explaining that API and capsule supply agreements met AstraZeneca business needs); 10/29/14 Tr. at 44 (AstraZeneca saved money through API supply agreement). Finally, the undisputed testimony was that Ranbaxy lost money on the tolling agreement. *See* 12/1/14 Tr. at 69.

Plaintiffs have no basis for arguing to the jury that the API supply and tolling agreements with Ranbaxy effected any unlawful payment to Ranbaxy.

4. Alleged Involuntary Relinquishment by Ranbaxy

Plaintiffs should not be permitted to argue to the jury a causation theory foreclosed by summary judgment, namely, Plaintiffs' theory of "involuntary relinquishment." This theory was that "even if Ranbaxy could not have met an earlier deadline, Ranbaxy would have lost its marketing exclusivity on the relinquishment date, opening the door for another firm, like Teva, to come to market before May 2014." ECF No. 977 at 88-89; *see also* ECF No. 1306 at 14 (arguing that Ranbaxy was faced with "the risk of involuntary relinquishment of its exclusivity on generic Nexium"). The Court foreclosed it because it "layers hypothetical scenario upon

hypothetical scenario, and as this Court routinely charges the jury, there must be no packing of inference upon inference." *Id.* at 89 (quotation marks omitted).

As the Court reiterated at the final pretrial conference, the theory remaining to being tried is one of voluntary relinquishment, *i.e.*, "that Teva would have made a joint launch with Ranbaxy who was first in line." 9/30/14 Tr. at 5. The jury likewise understands that this is the sole means by which Plaintiffs may show that Teva would have circumvented Ranbaxy's exclusivity: Plaintiffs must prove Teva would have "cut a deal with Ranbaxy, who's blocking it from entry under the Hatch-Waxman Act, so that they could jointly launch a generic." 10/21/14 Tr. at 42. The issue has also arisen at many sidebars, where Plaintiffs have conceded that they "will have to prove that there also had been a deal between Ranbaxy and Teva." 11/12/14 Tr. at 39.

Accordingly, Defendants seek an order precluding any argument concerning involuntary relinquishment.

5. Generalized Statements about What "Kind of Company" a Defendant Is

In opening statements, Plaintiffs informed the jury that the FDA had banned imports from Ranbaxy facilities and stated, "That's the kind of company that AstraZeneca decided to do a conspiracy with, the kind of company that gets shut down in terms of putting its imports into the United States." 10/21/14 Tr. at 73. Such aspersions about Defendants serve no purpose other than prejudicing jurors against Defendants and have no place in closing arguments. Plaintiffs may argue based on the evidence in the record—they should not be permitted to make generalized statements about the "kind of company" a Defendant is.

6. AstraZeneca Documents Purportedly Estimating Value of Ranbaxy Settlement

During trial, Plaintiffs attempted to elicit testimony that various AstraZeneca forecasting documents estimated the value of the AstraZeneca-Ranbaxy settlement to AstraZeneca. *See,*

e.g., 11/5/14 Tr. 30-32 (examination of Mr. Hester regarding Exhibit 14). The Court sustained AstraZeneca's objections to Plaintiffs' attempts to characterize the document as an estimate of the value of the AstraZeneca-Ranbaxy settlement. *See id*. at 33 (sustaining objection on the grounds that Plaintiffs' counsel "was asking a question that suggests that [Mr. Rowles] was creating this as a [sic] purpose of estimating the value of the settlement and there is no basis for that whatsoever").

Plaintiffs should be precluded from using AstraZeneca forecasts, e.g., Exhibit 14, to argue how AstraZeneca valued the AstraZeneca-Ranbaxy settlement.

7. Documents Produced During Trial that Had Been Withheld as Privileged

Plaintiffs should not be permitted to argue to the jury that there was anything improper with AstraZeneca's having withheld documents as privileged. As the Court explained to the jury, there is nothing improper about withholding documents for which there is a good-faith assertion of privilege: "You don't have to turn over documents that are privileged, documents where its the lawyer's advice to the client, the client being the company, or the company's requests to the lawyer, tell us about this and that. You don't have to turn over that." 10/29/14 Tr. at 139. Accordingly, Plaintiffs should not be permitted to argue that any privileged documents that the Court ordered produced, e.g., Exhibit 140, had been improperly withheld by any Defendant.

8. Conspiracy

Consistent with the Court's rulings on directed verdict, Plaintiffs should not be permitted to argue that there was any conspiracy between or among Defendants. 11/21/14 Tr. at 4 ("I don't want to hear the word 'conspiracy' as we go along here and we won't hear it in closing.").

9. Teva's Aggressive Litigation Would Be Leverage To Entice Ranbaxy To Partner with Teva

Plaintiffs asserted in opposition to defendants' motion for a directed verdict on causation that Teva's aggressive litigation strategy in the Nexium patent cases would have been leverage to entice Ranbaxy to partner with Teva to bring generic Nexium to market. *See* Pls.' Opp. to Defs.' Rule 50 Motion on Causation at 3. That assertion was made without any citation or support. And with good reason—there is no such evidence in the record. Plaintiffs should not be permitted to repeat this unsupported assertion to the jury.

10. Patent Validity

In a brief filed yesterday, Plaintiffs asserted that AstraZeneca had "abandoned their prior arguments concerning the outcome of the patent litigations" and, therefore, it had a "50/50" chance of losing the patent litigations. ECF No. 1340 at 3–4. This assertion is made up from whole cloth. No evidence exists to support it; moreover, the assertion is foreclosed by the Court's ruling that "there is no adequate evidence that any of these patents would be adjudicated invalid." 11/21/14 Tr. at 4-5. Accordingly, Plaintiffs should not be permitted to argue that the Nexium patents would have been found invalid. Nor should Plaintiffs be permitted to argue that AstraZeneca faced any risk of losing any of its rights under the Nexium patent estate, let alone argue to the jury the completely unsupported assertion that AstraZeneca faced a 50/50 chance of losing in the patent litigation.

11. Alleged Payment to Teva

Since the claims against Teva have been dismissed, Plaintiffs should not be permitted to argue to the jury regarding any alleged payment to Teva, including any argument that the Teva

settlement caused any disincentive or delay in Teva's ability to come to market with a generic Nexium product.[1]

CONCLUSION

Plaintiffs should not be permitted to make the foregoing arguments during closings.

Dated: December 2, 2014

Respectfully submitted,

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[1] In addition, for the reasons stated in Defendants' directed verdict motion on the alleged payment to Teva, Plaintiffs have offered no competent reasonable royalty opinion from which a jury could conclude there was any payment to Teva. *See* 11/12/14 Tr. at 4 (striking "so much of the testimony of McCool as comes up with his 55 percent plus 10 million upfront and also the dollar amounts of the supposed comparables"). Even if there were competent evidence of a reasonable royalty, there is no evidence that $9 million was an unfair compromise of the Teva Prilosec case. Nor is there evidence that Teva paid and AstraZeneca accepted an amount that was unreasonably low under all of the circumstances of the Prilosec litigation. In sum, Plaintiffs have failed to introduce any evidence to establish that AstraZeneca would have recovered substantially more than $9 million had it gone to trial against Teva in the Prilosec case or that the $9 million was substantially less than an amount appropriate to settle Teva's exposure.

CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of December 2014, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/ James H. Weingarten
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